



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/491,982	01/27/2000	Stephen Shaughnessy	1171-101	9313

28120 7590 10/15/2003

ROPES & GRAY LLP
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

MERTZ, PREMA MARIA

ART UNIT	PAPER NUMBER
----------	--------------

1646

DATE MAILED: 10/15/2003

26

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/491,982

Applicant(s)

SHAUGHNESSY ET AL.

Examiner

Prema M Mertz

Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,14 and 43-50 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,14 and 43-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☒ Certified copies of the priority documents have been received in Application No. 09/314,152.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☒ Interview Summary (PTO-413) Paper No(s). 24.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____. 6) ☐ Other:

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/03 has been entered.
2. Claims 2, 4-13, 15-42 have been canceled. Amended claims 1, 3, 14 and new claims 43-50 (Paper No. 25, 7/30/03) are pending and under consideration by the Examiner.
3. Receipt of applicant's arguments and amendments filed in Paper No. 25 (7/30/03) is acknowledged.
4. The following previous rejections and objections are withdrawn in light of applicants amendments filed in Paper No. 25, 7/30/03:
 - (i) the rejection of claims 2, 4, 11, 15-16 under 35 USC § 112, first paragraph;
 - (ii) the rejection of claims 1-5, 10-11, 15-16, 40-41 under 35 USC § 102 as being anticipated by WO 9619574; and
 - (iii) the rejection of claims 1-5, 10-11, 15-16, 40-41 under 35 USC § 103(a) as being unpatentable over Romas et al (1995) in view of WO 9619574.
5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim rejections-35 USC § 112, second paragraph

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7a. Claims 1, 3, 14, 43-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, line 4, incorrectly recites "inhibit" rather than "inhibits".

Regarding claim 45, the phrase "including" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claims 3, 14, 43-44, 46-50 are rejected under 35 U.S.C. 112, second paragraph, insofar as they depend on claim 1 for its limitations.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8a. Claims 1, 3, 14, 43-49 are rejected under 35 U.S.C. § 103 as being unpatentable over Girasole et al.

Girasole et al. discloses administering a neutralizing antibody to IL-11, as well as a monoclonal antibody to IL-11, to inhibit osteoclast formation in cocultures of marrow and calvaria cells (see abstract; see page 1518, lines 8-16; Table IV, page 1522). Girasole et al. fail to disclose a method of administering to a patient neutralizing or monoclonal antibodies to the IL-11 protein, said patient having a pathological condition in which bone density is decreased.

Therefore, it would have been prima facie obvious to one having ordinary skill in the art at the time the invention was made to use the method taught by Girasole et al., to administer monoclonal antibodies or neutralizing antibodies to patients having a pathological condition in which bone density is decreased, with the expectation that the IL-11 antibodies would decrease osteoclast-mediated bone resorption because Girasole et al. teach of the ability of IL-11 to induce osteoclast development (see Figure 1, page 1519) and the ability of IL-11 antibody to neutralize this activity of IL-11 (Table IV, page 1522).

Though the reference fails to teach an increase in osteoblast-mediated bone formation when an IL-11 antibody is administered to patients having a pathological condition in which bone density is decreased, this phenomenon would be inherent to the prior art process disclosed in the reference. It is not necessary that the prior art suggest the combination to achieve the same

Art Unit: 1646

advantage or result discovered by applicant. *In re Linter*, 458 F.2d 1013, 173 USPQ 560 (CCPA 1972); *In re Dillon*, 919 F.2d 688, 16 USPQ2d 1897 (Fed. Cir. 1990), cert. denied, 500 U.S. 904 (1991) (discussed below).

In *In re Dillon*, the court held “it is not necessary in order to establish a prima facie case of obviousness . . . that there be a suggestion or expectation from the prior art that the claimed [invention] will have the same or a similar utility as one newly discovered by applicant,” and concluded that here a prima facie case was established because “[t]he art provided the motivation to make the claimed compositions in the expectation that they would have similar properties.” 919 F.2d at 693, 16 USPQ2d at 1901 (emphasis in original). See MPEP § 2145, paragraph II for case law pertaining to the presence of additional advantages or latent properties not recognized in the prior art. Therefore, in view of *In re Dillon*, the prior art reference renders obvious the instant claims.

8b. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Girasole et al. (1994) in view of Queen et al. (U.S. Patent No. 5,530,101).

The disclosure of Girasole has been set forth above (see paragraph 8a above). However, Girasole does not disclose a method of using humanized monoclonal antibodies to IL-11 for inhibiting reduction of bone density in a patient.

Queen et al., (column 13, lines 5-65) teaches the humanization of monoclonal antibodies, as well as the issues involved in designing a humanized antibody that retains high affinity for its antigen. Queen et al., (column 17, lines 31-43) further teaches the production of antibody fragments, including the Fab fragment.

Art Unit: 1646

At the time the invention was made, it would have been prima facie obvious to a person of ordinary skill in the art to administer as taught by Queen et al., humanized monoclonal antibodies to IL-11 for inhibiting reduction of bone density in a patient in a method as taught by Girasole et al. The motivation for doing so would have been the decreased immunogenicity of humanized antibodies when injected into humans, while the humanized antibodies retain their affinity for their epitope (Queen et al., (column 2, lines 5-8)).

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (703) 308-4229. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 305-3014 or (703) 308-4242. Faxed draft or informal communications with the examiner should be directed to (703) 746-5300.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Prema Mertz
Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
August 28, 2003